



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

**Pfizer Inc**  
Pfizer Pharmaceuticals Group  
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CHEMTREC (24 hours): 1-800-424-9300

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ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Doxycycline calcium oral suspension syrup**

**Trade Name:** Vibramycin(R)  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as antibiotic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Doxycycline calcium	94088-85-4	302-088-9	1
Hydrogen chloride	7647-01-0	231-595-7	*
Magnesium aluminum silicate	1327-43-1	215-478-8	*
Calcium chloride USP	10035-04-8	Not listed	*
Glycerin, USP	56-81-5	200-289-5	*
Sodium hydroxide	1310-73-2	215-185-5	*
Sodium metabisulfite USP	7681-57-4	231-673-0	*

Ingredient	CAS Number	EU EINECS List	%
Sorbitol	6706-59-8	Not listed	*
Raspberry flavor	NOT ASSIGNED	Not listed	*
Butylparaben	94-26-8	202-318-7	*
Simethicone emulsion	67762-90-7	Not listed	*
Povidone	9003-39-8	Not listed	*
Propylparaben	94-13-3	202-307-7	*
Carmines no. 40 - FCC	NOT ASSIGNED	Not listed	*
Apple flavor, artificial	NOT ASSIGNED	Not listed	*
Propylene glycol	57-55-6	200-338-0	*
Water, purified	7732-18-5	231-791-2	*

### Additional Information:

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Raspberry-apple flavored syrup  
**Signal Word:** WARNING

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**Statement of Hazard:** Infants of mothers exposed during pregnancy may develop discoloration of the teeth  
May cause allergic reaction in sensitive individuals  
May cause liver toxicity

**Additional Hazard Information:**  
**Short Term:** May cause allergic reactions in susceptible individuals. Accidental ingestion may cause effects similar to those seen in clinical use.

**Known Clinical Effects:** May cause permanent discoloration of teeth if used during tooth development. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Photosensitivity has been reported in some individuals taking tetracyclines.

**EU Indication of danger:** Toxic to reproduction: Category 1

**EU Hazard Symbols:**



**EU Risk Phrases:** R63 - Possible risk of harm to the unborn child.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. FIRST AID MEASURES

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

**Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

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<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

<b>General Handling:</b>	Use with adequate ventilation. Avoid breathing vapor or mist. Wash thoroughly after handling.
<b>Storage Conditions:</b>	Keep container tightly closed when not in use. Store in a cool, dry place away from direct sunlight.
<b>Storage Temperature:</b>	<30°C

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Doxycycline calcium</b> Pfizer OEL TWA-8 Hr:	0.25 mg/m <sup>3</sup>
<b>Hydrogen chloride</b> ACGIH Ceiling Threshold Limit: Australia PEAK	= 2 ppm Ceiling = 5 ppm Peak = 7.5 mg/m <sup>3</sup> Peak
<b>Glycerin, USP</b> OSHA - Final PELs - TWAs: ACGIH Threshold Limit Value (TWA) Australia TWA	= 15 mg/m <sup>3</sup> TWA total = 5 mg/m <sup>3</sup> TWA = 10 mg/m <sup>3</sup> TWA = 10 mg/m <sup>3</sup> TWA
<b>Sodium hydroxide</b> OSHA - Final PELs - TWAs: ACGIH Ceiling Threshold Limit: Australia PEAK	2 mg/m <sup>3</sup> = 2 mg/m <sup>3</sup> Ceiling = 2 mg/m <sup>3</sup> Peak
<b>Sodium metabisulfite USP</b> ACGIH Threshold Limit Value (TWA) Australia TWA	= 5 mg/m <sup>3</sup> TWA = 5 mg/m <sup>3</sup> TWA
<b>Propylene glycol</b> Australia TWA	= 10 mg/m <sup>3</sup> TWA = 150 ppm TWA = 474 mg/m <sup>3</sup> TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

<b>Analytical Method:</b>	Analytical method available for Doxycycline. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.
<b>Personal Protective Equipment:</b>	

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**Hands:** Rubber gloves  
**Eyes:** Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Syrup	<b>Color:</b>	Red
<b>Odor:</b>	Light raspberry	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		

### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** Strong oxidizers  
**Hazardous Decomposition Products:** No data available See Section 5 - under Hazardous combustion products.  
**Polymerization:** Will not occur

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Hydrogen chloride

Rat Inhalation LC50 1H 3,124 ppm  
Mouse Inhalation LC50 1H 1,108 ppm  
Mouse Oral LD50 900 mg/kg

##### Sodium hydroxide

Mouse IP LD50 40 mg/kg

##### Propylene glycol

Mouse Oral LD50 22,000 mg/kg  
Rat Oral LD50 20,000 mg/kg  
Rabbit Dermal LD50 20,800 mg/kg

##### Povidone

Rat Oral LD50 100 g/kg

##### Propylparaben

Mouse Oral LD 50 6332 mg/kg  
Mouse Intraperitoneal LD 50 200 mg/kg

##### Glycerin, USP

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Mouse Oral LD50 4090 mg/kg  
Rat Oral LD50 12.6 g/kg  
Rabbit Dermal LD50 > 10 g/kg  
Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>  
Rat Dermal LD 50 >21.9 g/kg

### Calcium chloride USP

Rat Oral LD50 1000 mg/kg  
Mouse Oral LD50 1940 mg/kg

### Doxycycline calcium

Mouse Oral LD50 1900 mg/kg (hydrochloride)  
Rat Oral LD50 > 2000 mg/kg (hydrochloride)

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

**Inhalation Acute Toxicity** Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.

**Ingestion Acute Toxicity** See Acute toxicity table.

### Irritation / Sensitization: (Study Type, Species, Severity)

#### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

#### Propylene glycol

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

#### Glycerin, USP

Eye Irritation Rabbit Mild

#### Eye Irritation / Sensitization

Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.

#### Skin Irritation / Sensitization

Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered. Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines.

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system  
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

#### Subchronic Effects

Rats administered oral doses up to 500 mg/kg/day for 30 days showed no toxic effects. Chronic toxicity was evaluated in rats at oral doses up to 500 mg/kg/day for 18 months.

#### Chronic Toxicity

Findings revealed no adverse effects on growth, food consumption, or survival. Yellow ultraviolet fluorescence of bone, teeth and/or kidneys was seen in rats at all levels. Chronic studies in dogs at oral doses up to 100 mg/kg/day for one year showed some functional and histopathological changes in the liver. However, effects were reversible after cessation of exposure to the material.

#### Chronic Effects/Carcinogenicity

No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.

#### Reproductive Effects

Fertility studies of doxycycline in female rats at oral doses up to 250 mg/kg/day showed no adverse effects.

#### Teratogenicity

No teratogenic effects were observed in monkeys at oral doses of doxycycline HCl ranging from 1 to 50 mg/kg/day. Tetracyclines as a class are capable of crossing the placenta and causing permanent discoloration of the teeth. Liver Reproductive system

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<b>Mutagenicity</b>	No data available however, positive results in in vitro mammalian cell assays have been reported for related antibiotics.
<b>Carcinogen Status:</b>	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
<b>Hydrogen chloride IARC:</b>	Group 3
<b>Povidone IARC:</b>	Group 3
<b>Sodium metabisulfite USP IARC:</b>	Group 3
<b>At increase risk from exposure:</b>	Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure.
<b>Additional Information:</b>	FDA PREGNANCY CATEGORY D. Positive evidence of human fetal risk from marketing experience or human studies.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Glycerin, USP

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LD50	96 Hours	50 mg/L
<i>Daphnia Magna</i> (Water Flea)	EC50	24 Hours	>500 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

### 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

**EU Symbol:** T  
**EU Indication of danger:** Toxic to reproduction: Category 1

**EU Risk Phrases:** R63 - Possible risk of harm to the unborn child.

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## EU Safety Phrases:

S53 - Avoid exposure - obtain special instructions before use.

## OSHA Label:

WARNING

Infants of mothers exposed during pregnancy may develop discoloration of the teeth

May cause allergic reaction in sensitive individuals

May cause liver toxicity

## Canada - WHMIS: Classifications

### WHMIS hazard class:

Class D, Division 2, Subdivision A



## Doxycycline calcium

California Proposition 65

EU EINECS List

developmental toxicity, initial date 1/1/92 (internal use)

302-088-9

## Butylparaben

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present

Present

202-318-7

## Hydrogen chloride

CERCLA/SARA 313 Emission reporting

CERCLA/SARA Hazardous Substances  
and their Reportable Quantities:

CERCLA/SARA - Section 302 Extremely Hazardous  
TPQs

CERCLA/SARA - Section 302 Extremely Hazardous  
Substances EPCRA RQs

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling  
for Drugs and Poisons:

EU EINECS List

= 1.0 % de minimis concentration acid aerosols including mists,  
vapors, gas, fog, and other airborne forms of any particle size

= 2270 kg final RQ

= 5000 lb final RQ

= 500 lb TPQ gas only

= 5000 lb EPCRA RQ gas only

T

Present

Schedule 5

Schedule 6

231-595-7

## Simethicone emulsion

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

XU

Present

## Magnesium aluminum silicate

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present

Present

215-478-8

## Calcium chloride USP

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Australia (AICS):	Present
<b>Povidone</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
<b>Propylparaben</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7
<b>Glycerin, USP</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5
<b>Sodium hydroxide</b>	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	215-185-5
<b>Sodium metabisulfite USP</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS List	231-673-0
<b>Propylene glycol</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0
<b>Water, purified</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

**End of Safety Data Sheet**



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